

REMARKS

In the aforesaid Office Action, claims 33-36, 38 and 41 were rejected under 35 USC 103(a) as being unpatentable over Trotta (5,620,649) in view of Charbrecek et al. (6,447,920), and claims 33-37 and 41 were rejected under 35 USC 103(a) as being unpatentable over Zhong (6,048,620) in view of Charbrecek et al., and claim 39 was rejected under 35 USC 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Zhong, and claim 40 was rejected under 35 USC 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Okuda et al. Claims 33-36, and 38-42 are pending (claim 37 being canceled and new claim 42 being added by this amendment).

Applicants appreciate the courtesies extended by the Examiner in the telephone interview on May 4, 2004, conducted between Applicant's representative, Priscilla Morrison, and the Examiner. Applicant's summary of the interview is given below.

In the May 4, 2004 interview, claims 33 and 38, and the Zhong, Charbrecek et al., and Trotta patents were discussed. Applicants stated that Applicant's invention is related to providing a thin plasma polymerized layer on a layer of a balloon to improve bondability of the balloon layer, whereas Zhong discloses coating a balloon with a first layer such as an acrylic copolymer dispersion for bonding an outer hydrophilic coating and does not disclose a layer having a thickness within the range required by claim 33. The Examiner clarified that the rejections based on Charbrecek et al. as a secondary reference are based on the teaching in Charbrecek et al. of the desirability of a coating having a thickness within Applicant's claimed range. Applicants pointed out that the coating of Charbrecek et al. having a thickness within the

claimed range is an outer hydrophilic coating, so that the combination of Zhong in view of Charbrecek et al. at most modifies the outer hydrophilic coating of Zhong to have the thickness of the outer hydrophilic coating of Charbrecek et al. Applicants agreed to amend claim 33 to clarify that the plasma polymerized layer is a middle layer located between the first and second layers of the balloon. Applicants also discussed a proposed amendment to claim 38, to set forth an embodiment in which a section of the plasma polymerized layer on the first layer is between the first layer and the shaft.

The Examiner rejected claims 33-37 and 41 under 35 USC 103(a) as being unpatentable over Zhong in view of Charbrecek et al., stating that the balloon part of Zhong corresponds to the second layer of the claimed invention, the first coating of Zhong corresponds to the covalently bonded functionality of the claimed invention, the second coating of Zhong corresponds to the first layer of the claimed invention, and that although Zhong does not teach that their first coating has a thickness of about 10 to 150 nanometers, Charbrecek et al. discloses coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating with a coating thickness that can be controlled to be from 0.001 micrometer (equivalent to 1 nanometer) to 100 micrometers, and that it would have been obvious to one of ordinary skill in the art to optimize the thickness of the first coating (the covalently bonded functionality of the claimed invention) taught by Zhong given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Charbrecek et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 1 nm to 1,000,000 nm.

However, the 1 nm thick coating of Charbrecek et al. is a hydrophilic coating which forms an outer-most surface layer of the device. In contrast, in Zhong, the first coating is a middle layer, providing a bonding layer which bonds the second (outer-most) hydrophilic coating of Zhong to the balloon. Therefore, at most, the combination of Zhong in view of Charbrecek et al. modifies the outer hydrophilic coating of Zhong to have the thickness of the outer hydrophilic coating of Charbrecek et al. There is no motivation to combine the references in such a way as to modify the first (middle) coating of Zhong according to the teaching of Charbrecek et al. regarding Charbrecek's outer hydrophilic coating. Thus, the combination of Zhong in view of Charbrecek et al. does not render unpatentable Applicant's balloon having a plasma polymerized functionality located between the first and second layers of the balloon and having a thickness of about 10 to about 150 nanometers.

The Examiner rejected claims 33-36, 38 and 41 under 35 USC 103(a) as being unpatentable over Trotta in view of Charbrecek et al., and claim 39 under 35 USC 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Zhong, and claim 40 under 35 USC 103(a) as being unpatentable over Trotta in view of Charbrecek et al. and Okuda et al., stating that the first layers (10, 24) of Trotta correspond to the first and second layers of the claimed invention and the second layer (20) of Trotta corresponds to the covalently bonded functionality of the claimed invention, and that although Trotta does not teach that the second layer has a thickness of about 10 to 150 nm, Charbrecek et al. discloses coated biomedical devices having a bulk material coated with covalently bonded hydrophilic surface coating with a coating thickness that can be controlled to be from 0.001 micrometer (equivalent to 1 nanometer) to 100 micrometers, and that it would have been obvious to one of ordinary skill in the art to optimize

the thickness of the second layer (the covalently bonded functionality of the claimed invention) taught by Trotta given that the thickness of the first layer can be controlled by controlling the amount of crosslinking agent present in the solution and further given that Charbrecek et al. specifically teach that the coating thickness of a hydrophilic coating on a biomedical device can be controlled to obtain specific properties and the thickness can be controlled to be from 1 nm to 1,000,000 nm.

However, as discussed above in relation to the rejection based on Zhong in view of Charbrecek et al., the 1 nm thick coating of Charbrecek et al. is a hydrophilic coating which forms an outer-most surface layer of the device. In contrast, in Trotta, the three layers (10, 20, 24) are coextruded together, with the second layer (20) of Trotta being a middle layer, providing a soft middle layer which bonds the inner and outer first layers (10, 24) of Trotta together. Thus, Trotta's second layer (20) is a coextruded layer, unlike the separately applied coating layer of Charbrecek et al., and the second layer (20) is a central layer located between an inner and outer layer, unlike the outer-most coating layer of Charbrecek et al., and the second layer (20) is a soft, functionalized tie-layer polymer which has a different nature and purpose than hydrophilic coating of Charbrecek. Consequently, there is no motivation to combine the references in such a way as to modify the second (middle) layer (20) of Trotta according to the teaching of Charbrecek et al. regarding Charbrecek's outer hydrophilic coating. Thus, the combination of Trotta in view of Charbrecek et al. does not render unpatentable Applicant's balloon having a plasma polymerized functionality located between the first and second layers of the balloon and having a thickness of about 10 to about 150 nanometers.

Moreover, claim 38 sets forth an embodiment in which a section of the plasma polymerized functionality is between the first layer and the shaft. Support for the amendment to claim 38 can be found in the last sentence of paragraph [0021] (third full paragraph of the Detailed Description).

Applicants have added new claim 42, corresponding to claim 33 and additionally requiring that the plasma polymerized functionality is plasma polymerized acrylic acid.

In light of the above amendments and remarks, applicant respectfully requests reconsideration and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:

  
\_\_\_\_\_  
Gunther O. Hanke  
Registration No. 32,989

Howard Hughes Center  
6060 Center Drive, Tenth Floor  
Los Angeles, CA 90045  
Telephone: (310) 824-5555  
Facsimile: (310) 824-9696  
Customer No. 24201

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